

PwD Letter

Urgent Field Safety Notice



<Enter address here>

Location, Date 2014

Important notice:

Enhanced instructions for proper testing with the Accu-Chek[®] Mobile system to avoid the potential of falsely elevated blood glucose readings

Dear Customer,

As a valued Accu-Chek[®] Mobile user, we would like to inform you that we are introducing enhanced handling instructions and training for the use of the Accu-Chek Mobile system.

As the strip-free Accu-Chek[®] Mobile blood glucose monitoring system offers a unique testing procedure, it also requires particular awareness of its proper handling. Being in close contact with its customers worldwide, Roche Diabetes Care has identified that a small number of people with diabetes using the Accu-Chek[®] Mobile device have experienced falsely elevated blood glucose readings when using the system as a result of not following the described and labelled handling instructions. Such improper handling can include, for example, unclean hands contaminated with glucose-containing substances, pressing the finger too hard and too long on the test field or smearing the blood while performing a test.

As your safety is our primary concern, Roche Diabetes Care has decided to substantially enhance its training and handling instructions for the Accu-Chek[®] Mobile system. This will help ensure you obtain safe and reliable blood glucose (bG) readings at all times. Please find attached the new training leaflet. You will also be able to access important training information online via [www. accu-chek.com/ \[insert country URL\]](http://www.accu-chek.com/[insert country URL])

You can continue to use your Accu-Chek[®] Mobile device safely and reliably by carefully following the instructions that are described in your Accu-Chek[®] Mobile User Manual and which are also included in the new training leaflet



- Wash your hands with warm water and soap. Dry your hands thoroughly before obtaining a blood sample
- Form a proper blood drop and apply it to the centre of the test field
- Immediately apply the blood gently to the test field after you have created the blood drop.
- Do not press against the test field on the tape
- Touch the test area gently and remove your finger immediately after having applied the blood
- Your finger should be removed from the test field when the beep tone sounds and/or "test in progress" is displayed

If you are concerned about the accuracy of a particular bG reading, please refer to the possible sources of error listed in the user manual and perform a test with a control solution. If all of the conditions for testing have been satisfied and you still feel concerned about a reading, please contact your healthcare provider and follow the individual advice.

To ensure maximum awareness of the enhanced handling instructions, we have informed regulatory bodies and healthcare professionals.

We thank you for your understanding and for your cooperation. Should you have any additional questions or seek clarification, please contact our Accu-Chek® Care Line on xxx-xxx-xxxxxx or your Roche representative.

Sincerely,

Roche Diabetes Care

Attachments: Proper testing instructions; Faxback /acknowledgement form